REMARKS

Claims 1-3, 5-7, 10, 12, 14, and 16-26 have been examined. Claims 1, 2, 14, 17, 20, 21, 25, and 26 have been amended. Claims 9 and 15 have been canceled. Claim 27 has been added. Dependent claims 4, 8, 11, and 13 stand withdrawn as being drawn to a non-elected species. Currently, claim 1 is generic. Re-examination and reconsideration of the pending claims 1-8, 10-14, and 16-26, as amended, are respectfully requested.

Amendment to Specification/Drawings

Applicants have added Fig. 9A and accompanying text in the specification directed at the blunt cannula as set forth in originally filed claim 22 pursuant to 37 C.F.R. § 1.83(a) and Examiner's instruction. These amendments are further supported in the original disclosure on page 6, lines 1-7. Applicants have also added reference numeral 86 to Fig. 5B to correct an inadvertent clerical error. These amendments are supported in the originally filed specification and claims and as such no new matter has been added thereby.

Formal Matters

Claims 21, 25, and 26 have been amended to correct the alleged informalities. No new matter is added thereby.

Substantive Rejections

Claims 1-3, 5, 7, 10, 12, 14, 16-20, 21, 23, 25, and 26 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,290,263 issued to Wigness et al. Claims 6 and 22 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wigness et al. in view of U.S. Patent No. 4,569,675 issued to Prosl et al. Claims 24-26 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wigness et al. in view of U.S. Patent No. 6,162,238 issued to Kaplan et al. Such rejections are traversed in part and overcome in part as follows.

In order to expedite prosecution of this case and to more clearly claim the present invention, Applicants have amended independent claim 1 to recite an implantable port comprising a port body having a flow passage therethrough and a pressure-responsive valve. The flow passage has an upstream end and a downstream end, wherein at least a portion of the upstream end is adapted to sealingly engage an access tube which is inserted into said upstream end. The pressure-responsive valve element is positioned in the flow passage within the port body downstream from the upstream portion so that an access tube can be fully inserted into said upstream portion without engaging the valve component, wherein the valve component is closed in the absence of a differential pressure above a threshold level. Such a pressure-responsive valve element positioned in the flow passage within the port body has not been reasonably disclosed or suggested by the cited art.

As the Examiner certainly knows and appreciates, the cited reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claims." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1912, 1920 (Fed. Cir. 1989). The Wigness et al. reference is clearly distinguishable from claim 1. In particular, with reference to Fig. 1B, Wigness et al. describes positioning a bi-directional check valve assembly (24) only at a distal end of a catheter (22) which is connected to an implantable manifold (28). The objective of the Wigness et al. check valve is to prevent blood components from clotting the tip of the catheter as well as to inhibit the backflow of blood into the catheter to prevent thrombus formation within the catheter lumen. See col. 3, lines 29-34.

The presently claimed invention of claim 1, in contrast, sets forth (even prior to amendment) that the valve element (40) is positioned in the flow passage (20) within the port body (11). Application, Fig. 1. By such positioning, the present invention aims to prevent forward flow of blood into a catheter (30) from the port (11) as well as to inhibit back bleeding or fluid backflow into a tissue tract (TT) overlying the port after

withdrawal of the access tube. Application, page 13, lines 27-33. Applicants further believe that the claimed valve element located within the port of claim 1 could not be reasonably suggested by Wigness et al. as this reference clearly teaches against such a modification as the implantable manifold (28) includes a self-sealing septum (29) at an upstream end through which a needle can be inserted to inject fluid into the manifold. Col. 4, lines 51-54. As such, there would be no motivation to modify the Wigness et al. device to include a valve element within the port.

Hence, absent any cited teaching or motivation for an implantable port comprising a pressure-responsive valve element positioned in the flow passage within the port body as now clearly recited in claim 1, claim 1 (and dependent claims 2-8, 10-14, 16 and 26) are now in condition for allowance.

Amended independent claim 17 recites a method for delivering a substance to a subcutaneous target site. The method similarly comprises, in part, percutaneously introducing an access tube to an implanted port having a flow passageway with an upstream end, a downstream end, and a valve element in the flow passageway within the port, wherein the access tube is introduced to seat in the passage but does not engage the valve element. Such a requirement for opening the valve within the port, as discussed above with respect to claim 1, is contraindicated by the Wigness et al. patent which teaches a valve only at a distal end of the catheter. Hence, claim 17 (and dependent claims 18-23) are allowable for many of the reasons given above regarding claim 1.

With respect to independent claim 24, Applicants respectfully note that the Kaplan et al. reference has an effective filing date of February 24, 1999. The present application is a continuation-in-part of and claims priority from Application No. 09/239,411 filed on January 28, 1999. Applicants believe that claims 24-26 are fully supported under 35 U.S.C. § 112 in the '411 parent application. Hence, under M.P.E.P. § 706.02, the Kaplan et al. reference does not appear to be prior art to the present application, and as such, Applicants respectfully request that the § 103(a) rejection be withdrawn and claim 24 (and dependent claims 25 and 26) be allowed.

Added Claim

Applicants have added dependent claim 27 to more fully claim the present invention. Support for added claim 27 is found in Fig. 1 and accompanying text on page 5, lines 1-9.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

On page 7, line 13, before the word "and" please insert the following paragraph:

Fig. 9A illustrates use of a blunt cannula for accessing the implanted port through an established tissue tract according to the methods of the present invention;

On page 14, starting at line 5, please insert the following paragraph:

In some cases, after the access tissue tract is established ETT, it will not be necessary to provide a sharpened element in order to assist in percutaneous introduction, as shown in Fig. 8. That is, a blunt cannula BC may be able to pass inwardly through the established tissue tract ETT, as shown in Fig. 9A. Usually, the blunt cannula will have a diameter which is larger than that of the tissue tract which will have collapsed after the needle was removed in the previously described treatment protocol. Thus, as the blunt cannula is introduced through the established tissue tract, the tissue tract will be dilated.

IN THE CLAIMS:

1. (Amended) An implantable port comprising:

a port body having a flow passage therethrough, said flow passage having an upstream end and a downstream end, wherein at least a portion of the upstream end is adapted to sealingly engage an access tube which is inserted into said upstream end; and

a pressure-responsive valve element positioned in the flow passage within the port body downstream from the upstream portion so that an access tube can be fully inserted into said upstream portion without engaging the valve component, wherein the valve component is closed in the absence of a differential pressure above a threshold level.

2. (Amended) An implantable port as in claim 1, wherein said port body comprises a housing and a housing insert coupled to said housing.

Please cancel claim 9.

14. (Amended) An implantable port as in claim 1 wherein the flow passage further comprises a catheter coupled to said port body wherein said catheter has a lumen fluidly coupled to said passage in the port body.

Please cancel claim 15.

17. (Amended) A method for delivering a substance to a subcutaneous target site, said method comprising:

percutaneously introducing an access tube to an implanted port having a flow passageway with an upstream end, a downstream end, and a valve element in the flow passageway within the port, wherein the access tube is introduced to seat in the passage but does not engage the valve element; and

introducing said substance into the flow passage through the access tube at a pressure sufficient to open the valve element to permit flow through the flow passageway to the target site.

20. (Amended) A method as in claim 17 further comprising locating the port by manually **[annually]** feeling the port to determine the position of the aperture.

21. (Amended) A method as in claim 17, wherein percutaneously introducing further comprises introducing the access tube **[is introduced]** through a skin layer overlying the implanted port having a thickness in the range from 3 mm to 20 mm.

25. (Amended) A kit as in claim 24 **[18]**, further comprising a penetrating element.

26. (Amended) A kit as in claim 25 **[19]**, wherein the penetrating element comprises a syringe needle.

27. (New) An implantable port as in claim 2, wherein the pressure-responsive valve element is integrally formed in the housing insert.